

### REMARKS

Upon entry of this Amendment, claims 7-12, 19, and 20 are pending in the application and stand rejected. Claims 1-6, 13-18, and 21-32 have been withdrawn from consideration. By this Amendment, claim 9 has been amended to correct a typographical error, and new claims 33-35 have been added to further highlighted the features of the claimed invention, and find support, for example at page 5, paragraphs [0040]-[0042] of the application. Entry of these changes is respectfully requested.

### REJECTION UNDER 35 U.S.C. § 103

Claims 7-12, 19, and 20 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kryzsik (U.S. Patent No. 6,534,074) in view of Shimizu (U.S. Patent No. 6,308,898) alone or further in view of Lanzendorfer. Applicants respectfully traverse this rejection and request reconsideration.

To establish a *prima facie* case of obviousness based on a combination of references, MPEP § 2142 states that the following criteria must be met:

- 1) "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings";
- 2) "there must be a reasonable expectation of success"; and
- 3) "the prior art reference (or references when combined) must teach or suggest all the claim limitations".

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness with respect to the combination of Kryzsik, Shimizu, and Lanzendorfer.

First, Applicants submit that there is no suggestion or motivation in the cited references to arrive at the present invention. Applicants submit that Kryzsik discloses an oil based – hydrophobic composition that is applied to "the body facing material" of a disposable absorbent articles to provide skin barrier enhancing properties (see, for example, column 2, lines 51-55). According to Kryzsik, the composition is applied to the bodyside material of an absorbent article to protect, maintain or recover skin barrier against irritants in biological fluids (see, for example, column 2, lines 38-41). Kryzsik

further describes the composition as a solid at room temperature. This solid composition is heated for application onto the absorbent body facing material and re-solidifies rapidly so that it will remain on the surface of the body facing material and not migrate into the inner layers of the absorbent material (see, for example, column 3, lines 10-15). However, as stated in the Office Action Kryzski fails to disclose squalene and tocols in the amounts set forth in the claims of the present invention.

To overcome this deficiency, the Examiner relies on Shimizu. Shimizu discloses a composition that contains squalene and Vitamin E (tocopherol). The Examiner concludes that it would have been obvious to provide a source of tocol to the skin treatment of Krzysik to enhance the skin treatment properties of the ointment without the inclusion of hormones. Applicants respectfully disagree with this conclusion because there is no suggestion or motivation in Kryzsk for applying the composition directly onto the skin instead of applying onto the body facing material of an absorbent article. Further Applicants submit that Shimizu and Lanzendorfer likewise fails to provide any suggestion or motivation for the proposed combination.

As such, Applicants submit that no persuasive motivation or suggestion has been provided why one skilled in the art would combine the cited portions of Kryzsk with those of Shimizu or Lanzendorfer, other than to obtain Applicants' claimed invention, a motivation that could only come from Applicants' own disclosure. Therefore, Applicants respectfully submit that a *prima facie* obviousness rejection has not been presented, because there is no motivation or suggestion to combine the cited teachings of Kryzsk with those of Shimizu alone or further in view of Lanzendorfer, as the Examiner has combined them, contrary to the MPEP § 2143.

The cited section of the MPEP further provides that: "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (Emphasis added.) Contrary to the requirements of the MPEP, Applicants submit that portions of the cited references have been taken piecemeal in rejecting the claims of the application, while accompanying portions of these same references have been disregarded.

Applicants respectfully further submit that combining the references in the manner that the Examiner has combined them might well change the principle of operation of the cited references. The MPEP states in Section 2143.01 that: " If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." As previously discussed, Kryzsik teaches a composition that is a solid at room temperature and the resolidification of the melted oil based-hydrophobic composition occurs almost instantaneously when applied to the body facing material (see, for example, column 11, lines 25-44). Kryzsik also teaches that softer, creamier formulations are not suitable for application onto the body facing materials because they do not remain on the surface of the body facing material and migrate in the absorbent materials (see, for example, column 11, lines 64-67 to column 12, lines 1-9). As such, only solids or semi-solids are suitable for use in Kryzsik (see, for example, column 16, lines 43-46), and the use of a composition that is not a solid would change its principle of operation of Kryzsik.

As such, Kryzsik teaches away from the proposed combination with Shimizu because it states that the softer, creamier formulations disclosed in Shimizu are not suitable for use. The dosage forms for the external preparations of Shimizu are not solids or semi-solids as required in Kryzsik; but rather, are described as ointment, liniment, lotion, cream, paste, jelly, gel, emulsion, solution, cataplasm, or poultices; all of which are liquid or semi-liquid preparations which are characteristically soft, creamy and even greasy in nature (see, for example, column 4, lines 66-67 to column 5, lines 1-13). Therefore, there is no likelihood for success for the proposed combination. In fact, one skilled in the art might well expect these two formulations to interfere with one another. Thus, there is certainly a lack of motivation to combine such teachings together. Thus, Applicants respectfully submit that the cited portions of Kryzsik, Shimizu, and Lanzendorfer have been taken in piecemeal fashion in an attempt to reconstruct Applicants' invention using impermissible hindsight.

There is likewise no reasonable expectation of success, if such teachings were properly combined, in contravention of the MPEP, Section 2143.02, entitled

"Reasonable Expectation of Success is Required." Because of the divergent teachings of the two references, Applicants respectfully submit that there could be no reasonable expectation of success even if such references were properly combined, though Applicants respectfully submit that they were not. Applicants respectfully submit further that neither Kryzsik, nor Shimizu, nor Lanzendorfer supply the missing motivation to combine references as the Examiner has combined them. Accordingly, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness with respect to the modification of Kryzsik with Shimizu or Lanzendorfer and withdrawal of this rejection is respectfully requested. Applicants respectfully further submit that new claims 33-35 are likewise not made obvious by the combination of the cited references for the reasons discussed above.

Application No. 10/659,620  
Amendment dated December 18, 2006  
Reply to Office action dated August 18, 2006

80005(US01)


In summary, Applicants believe the application to be in condition for allowance. Accordingly, the Examiner is respectfully requested to reconsider the rejection(s), enter the above amendment, remove all rejections, and pass the application to issuance.

Applicants respectfully requests that a timely Notice of Allowance be issued in this case. Should the Examiner have any questions, please contact the undersigned at (423)-229-8862.

The Commissioner is hereby authorized to charge any additional fees that may be required, or to credit any overpayment, to Deposit Account No. 05-0221.

Respectfully submitted,

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Date

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Mail Stop Amendment, P. O. Box 1450, Alexandria, VA 22313-1450.

  
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Heather N. Ferguson

12-18-06  
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